Serial No. 09/715,902
Docket No. PP01627.003

CLAIM AMENDMENTS:

1. (Currently amended) A method of transfecting dendritic cells comprising:

providing dendritic cells;

providing a transfection agent comprising ~~a~~ polynucleotide adsorbed on surfaces of ~~and~~ microparticles, said ~~microparticles~~ transfection agent being formed by a process that comprises: (a) providing microparticles comprising a biodegradable polymer and a cationic detergent, and (b) exposing said microparticles to said polynucleotide, said polynucleotide encoding an antigen associated with a virus, a bacterium, a parasite, a fungus or a tumor; and

incubating the dendritic cells and the transfection agent *ex vivo* for a time sufficient to transfect the dendritic cells with the polynucleotide, thereby leading to the expression of said antigen.

2. (Original) The method of claim 1, wherein the dendritic cells originate from bone marrow.

3. (Original) The method of claim 1, wherein the dendritic cells originate from blood.

4. (Original) The method of claim 1, wherein the dendritic cells originate from a vertebrate subject.

5. (Previously presented) The method of claim 1, wherein the dendritic cells originate from a human subject.

6. (Previously presented) The method of claim 1, wherein the cationic detergent is cetyl trimethyl ammonium bromide.

7. (Previously presented) The method of claim 1, wherein the cationic detergent is cetrimide.

8. (Original) The method of claim 1, wherein the polymer is a poly(α-hydroxy acid).

9. (Original) The method of claim 1, wherein the polymer is a poly(lactide).

10. (Original) The method of claim 1, wherein the polymer is a copolymer of D,L-lactide and glycolide or glycolic acid.

11. (Original) The method of claim 1, wherein the polymer is a poly(D,L-lactide-co-glycolide).

12. (Original) The method of claim 1, wherein the polymer is a copolymer of D,L-lactide and caprolactone.

13. (Original) The method of claim 1, wherein the dendritic cells are cultured for about 5 days prior to transfection.

14. (Previously presented) The method of claim 1, wherein the dendritic cells are cultured for about 5 to about 10 days prior to transfection.

15. (Original) The method of claim 1, wherein the dendritic cells and transfecting agent are incubated for about 24 hours.

16. (Previously presented) The method of claim 1, wherein said polynucleotide is provided in the form of a plasmid.

17. (Cancelled)

18. (Currently amended) The method of ~~claim 17~~ claim 1, wherein the antigen is associated with human immunodeficiency virus, herpes simplex virus, hepatitis B virus,

hepatitis C virus, human papillomavirus, influenza A virus, meningitis A, meningitis B, or meningitis C.

19. (Currently amended) A method for producing an immune response comprising administering, to a vertebrate subject in need thereof, an effective amount of dendritic cells produced by the method of ~~claim 17~~ claim 1.

20. (Original) The method according to claim 19, in which the dendritic cells originate from the vertebrate subject.

21. (Original) The method according to claim 19, in which the dendritic cells originate from a healthy vertebrate subject MHC-matched to the vertebrate subject.

22. (Original) The method according to claim 19, in which the dendritic cells are administered parenterally.

23. (Original) The method according to claim 19, in which the dendritic cells are administered by direct injection into affected tissue.

24. (Cancelled)
25. (Cancelled)
26. (Cancelled)
27. (Cancelled)
28. (Cancelled)

29. (Currently amended) Antigen presenting dendritic cells made by the method of ~~claim 17~~ claim 1.

30. (Previously presented) The method according to claim 1, wherein said microparticles have diameters ranging from about 500 nm to about 30 μm.

31. (Original) The method according to claim 1, wherein said transfection agent contains on the order of 1% w/w polynucleotide.

32. (Cancelled)

33. (Currently amended) The method of ~~claim 17~~ claim 1, wherein said polynucleotide encodes a viral antigen.

34. (Currently amended) The method of ~~claim 17~~ claim 1, wherein said polynucleotide encodes a tumor antigen.

35. (Currently amended) The method of ~~claim 17~~ claim 1, wherein said polynucleotide encodes a bacterial antigen.

36. (Currently amended) The method of ~~claim 17~~ claim 1, wherein said polynucleotide encodes a parasitic antigen.

37. (Currently amended) The method of ~~claim 17~~ claim 1, wherein said polynucleotide encodes a fungal antigen.

38. (Previously presented) The method of claim 19, wherein said polynucleotide encodes a viral antigen.

39. (Previously presented) The method of claim 19, wherein said polynucleotide encodes a tumor antigen.

40. (Previously presented) The method of claim 19, wherein said polynucleotide encodes a bacterial antigen.

41. (Previously presented) The method of claim 19, wherein said polynucleotide encodes a parasitic antigen.

42. (Previously presented) The method of claim 19, wherein said polynucleotide encodes a fungal antigen.

43. (Previously presented) The method of claim 19, wherein said polynucleotide encodes a human immunodeficiency virus antigen, a herpes simplex virus antigen, a hepatitis B virus antigen, a hepatitis C virus antigen, a human papillomavirus antigen, an influenza A virus antigen, a meningitis A antigen, a meningitis B antigen, or a meningitis C antigen.

44. (Previously presented) The method of claim 19, wherein the detergent is cetyl trimethyl ammonium bromide.

45. (Cancelled)

46. (Previously presented) The method of claim 1, wherein at least a portion of said polynucleotide is entrapped within said microparticles.

47. (Cancelled)
48. (Cancelled)
49. (Cancelled)

50. (Previously presented) The method of claim 19, wherein at least a portion of said polynucleotide is entrapped within said microparticles.

51. (Cancelled)

52. (Currently amended) The method of any of claims 1-7, 13-23, 29-31, 33-44, 46 and ~~50 and 46-51~~, wherein the polymer is a poly(lactide-co-glycolide).

53. (Currently amended) The method of any of claims 1-15, 19-23, ~~29-32~~ 29-31, 44, 46 and 50, ~~and 46-51~~ wherein the polynucleotide is an expression vector encoding an antigen associated with a virus, a bacterium, a parasite, a fungus or a tumor.

STATUS OF CLAIMS

Claims 1-16, 18-23, 29-31, 33-44, 46, 50, 52 and 53 are presently pending, claims 17, 24-28, 32, 45, 47-49 and 51 having been cancelled without prejudice or disclaimer. Claims 24-28 have been cancelled as they are drawn to a non-elected invention. Remaining claim cancellations, as well as claim amendments, are made as a result of the incorporation of the subject matter of claims 17 and 45 into claim 1. No new issues are raised by the amendment.

REMARKS

Claims 1-23 and 29-53 are rejected under 35 U.S.C. 103(a) as obvious over Song et al. in view of Hedley et al. and Fattal et al. Applicants respectfully traverse this rejection and its supporting remarks.

In order to establish a *prima facie* case of obviousness under 35 U.S.C. 103, (a) there must be some suggestion or motivation to modify/combine the references of record, and (b) there must be a reasonable expectation of success. See MPEP §2143. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *Id.* The mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination or modification. MPEP 2143.01 (emphasis added) (citing *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)).

Claim 1, the only independent claim presently pending, reads as follows:

> 1. A method of transfecting dendritic cells comprising:
> providing dendritic cells;
> providing a transfection agent comprising polynucleotide adsorbed on surfaces of microparticles, said transfection agent being formed by a process that comprises: (a) providing microparticles comprising a biodegradable polymer and a cationic detergent, and (b) exposing said microparticles to said polynucleotide, said polynucleotide encoding an antigen associated with a virus, a bacterium, a parasite, a fungus or a tumor; and
> incubating the dendritic cells and the transfection agent *ex vivo* for a time sufficient to transfect the dendritic cells with the polynucleotide, thereby leading to the expression of said antigen.